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10/582,820

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Lyian He

03-903-US

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09/23/2009

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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

09/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                  |  |
|------------------------------|--------------------------------------|----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/582,820 | <b>Applicant(s)</b><br>HE ET AL. |  |
|                              | <b>Examiner</b><br>Bradley L. Sisson | <b>Art Unit</b><br>1634          |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>14 June 2006</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Drawings***

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because:
- a. Figure(s) 1-6 is/are not properly labeled. See 37 CFR 1.84(u)(1).
  - b. The lines are not clean, well-defined, and of uniform thickness in Figure(s) 1-6. See 37 CFR 1.84(l) and (q).
  - c. The shading in Figure(s) 1-6 is of poor quality and does not sufficiently contrast with the rest of the drawing(s). See 37 CFR 1.84(m).
  - d. Each panel needs to be individually labeled, e.g., FIG. 1A, FIG. 1B, etc. See 37 CFR 1.84(u)(1) and (2),
3. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The

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corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

## **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

### **Replacement Drawing Sheets**

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

### **Annotated Drawing Sheets**

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is indefinite with respect to what constitutes the metes and bounds of a “molecular motor.” While page 7 of the disclosure does provide statements as to what it could be, the statements are exemplary and non-limiting.

7. At page 7 of the disclosure applicant teaches that the “molecular motor” comprises a “biomolecular motor.” The metes and bounds of a “biomolecular motor” cannot be readily determined.

8. Claim 1 is indefinite with respect to what constitutes the metes and bounds of “directly adjacent.”

9. Claim 1 is indefinite with respect to what constitutes the metes and bounds of a “detection probe.” Acknowledgement is made of the definition provided at page 10 of the disclosure. Said definition, however, is exemplary and non-limiting.

10. Claims 2-7, which depend from claim 1, fail to overcome these issues and are similarly rejected.

11. Claims 5 and 6 are indefinite with respect to what constitutes the metes and bounds of “an elemental metal nanorod.” A review of the disclosure finds the expression being used but twice- first at page 10, line 5, and then in claim 5. No definition for the expression is provided.

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12. Claim 7 is incomplete. As presently worded, the method of claim 1 requires one to use a “detection probe.” The detection probe is not defined as having any property that would result in the production of light, much less “an oscillation of intensity of light,” as is required in claim 7.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15. As set forth in *In re Alonso* 88 USPQ2d 1849 (Fed. Cir. 2008), at 1851:

The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: “The specification shall contain a written description of the invention ....” To satisfy this requirement, the specification must describe the invention in sufficient detail so “that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997); *see also LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 [76 USPQ2d 1724] (Fed. Cir. 2005); *Eiselstein v. Frank*, 52 F.3d 1035, 1039 [34 USPQ2d 1467] (Fed. Cir. 1995).

*Alonso* at 1852:

A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its “relevant identifying characteristics,” such as “complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Enzo*, 323 F.3d at 964.

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16. In applying the test as set forth in *Alonso*, it is noted that applicant is claiming a generic method of detecting any nucleic acid of interest, be it singly or in a simultaneous manner, and without regard to presence of highly similar nucleic acids present in a sample that may be highly heterogeneous. In accordance with claim 1, the sole independent claim under consideration, one is to use first and second nucleic acids that hybridize to the target nucleic acid, and that these two hybridized nucleic acids are ligated to one another and then allowed to bind to any member of the genus of "a molecular motor" and any member of a "detection probe." Ultimately, one is to deduce the presence of a target nucleic acid by detecting "movement of the molecular motor," which in accordance with claim 7, is inferred by detection of "an oscillation of intensity of light at one or more wavelengths from the detection probe."

17. The specification has not been found to provide an adequate written description of the genus of molecular motors, detection probes, light-producing means whose intensity of emitted light "oscillates" in response to "movement" of the "molecular probe."

18. A review of the disclosure finds a Sequence Listing of but four oligonucleotides. These four oligos are either "artificial" (SEQ ID NO. 1) or "synthetic" (SEQ ID NOs. 2-4).

19. A review of the disclosure fails to find where applicant has provided an adequate written description of the genera of "first" and "second" nucleic acids, molecular motors, and detection probes so as to reasonably suggest that applicant was in possession of the generic method of detection.

20. Applicant teaches at page 24 of the disclosure that two software programs have been developed so to count photons, and that the use of the software is the preferred method to

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determine if there is any rotation. A review of the application, however, fails to find where applicant has disclosed the software for either platform.

21. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

22. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

23. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As presently claimed, the method of claims 1-7 fairly encompasses the detection of any and all manner of nucleic acids, including simultaneous detection of an infinite number of nucleic acids that have differing binding specificities.



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24. The method of claim 1 requires one to employ a first and second nucleic acid and that a “detection probe” is to bind to the second nucleic acid via an affinity tag.

25. The method does not require the removal of non-hybridized nucleic acids, or the removal of any other component, e.g., molecular motor and/or detection probe, prior to performing any detection. It is noted that one is not actually detecting any nucleic acid, but rather, is deducing presence of the target nucleic acid as a result of signal emanating from the detection probe. It stands to reason that retention of the detection probe, such as by non-specific binding, or complexation with second nucleic acid that has not hybridized to target, would fairly result in the production of a signal. Absent some means and method steps that would result in the production of a meaningful signal, one would not be able to determine which, if any, signal is actually informative.

26. The claimed method does not require one to employ the use of any control, be it positive and/or negative. Accordingly, one of skill in the art would not be able to determine if any signal is either informative or actually false.

27. As presently worded, the method encompasses the detection of multiple target nucleic acids in a simultaneous manner. The specification is silent as to how such an embodiment can be achieved.

28. Applicant is claiming a generic method of detecting any and all manner of nucleic acid targets, yet has not provided an adequate teaching of those essential reaction components that would be required to fully enable the claimed generic method. In support of this position, it is noted that the four sequences actually disclosed are either artificial (SQ ID NO. 1) or synthetic (SEQ ID NO. 2-4). A review of the disclosure fails to find a disclosure of first and second nuclei

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acids that hybridize “directly adjacent” to one another on any and all manner of target nucleic acids, much less a disclosure that enables the full scope of molecular motors and detection probes.

29. As noted above, applicant teaches that the preferred method for quantification of photons is by application of either software platform that applicant has produced. However, the application does not disclose either platform or any other platform that would enable said quantification.

30. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* (Fed. Cir. 1997) 42 USPQ2d 1001. As set forth in the decision of the Court:

“‘[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.’ *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (‘[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.’).

\*\*\*\*\*

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

“It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a

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specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

31. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

### ***Claim Rejections - 35 USC § 102***

32. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

33. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2003/0215844 A1 (Chapsky et al.)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

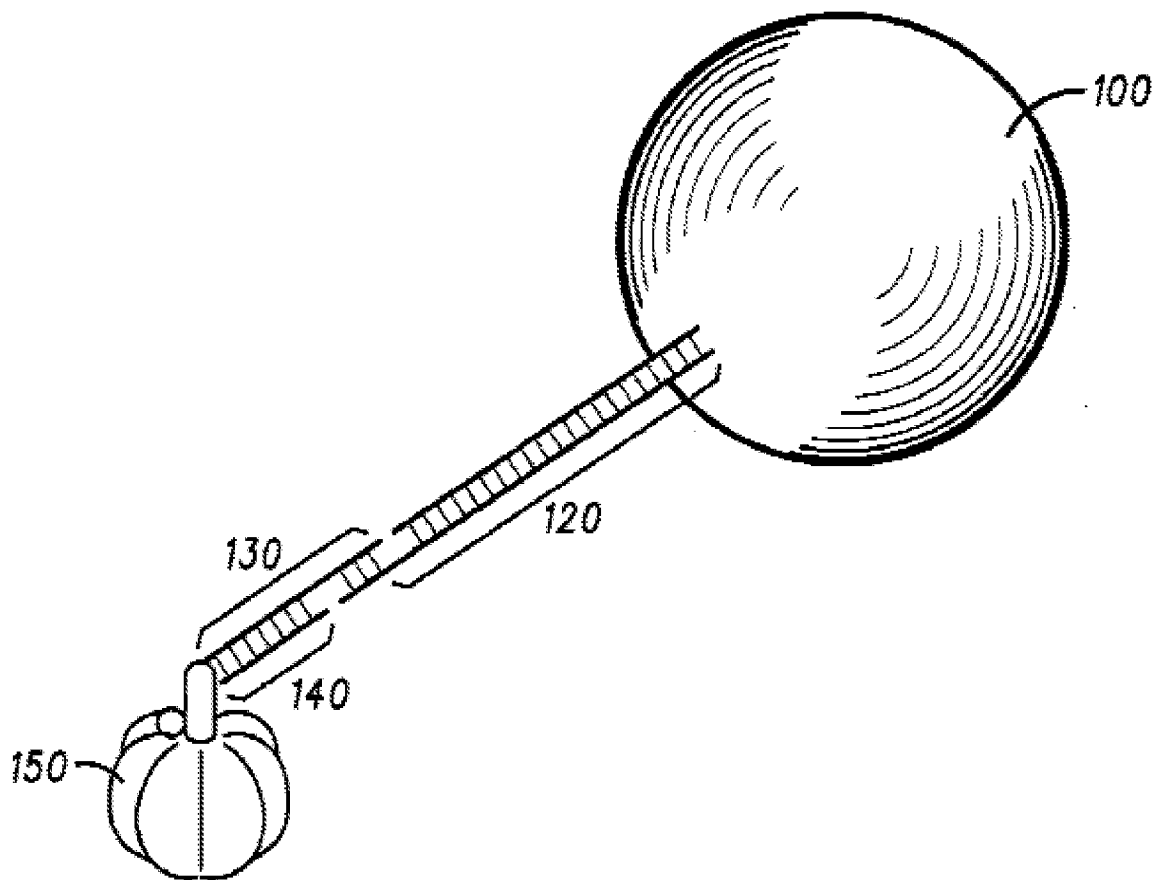
102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

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CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Chapsky et al. disclose a method of detecting a target nucleic acid. As set forth in the abstract they disclose

[a] method of employing DNA hybridization for the detection of bio-agents is disclosed as comprising inter alia a biomolecular rotary motor (150); a capture probe DNA fragment (140) effectively attached to said biomolecular motor (150); a target DNA fragment (130) suitably adapted for hybridization with said capture probe DNA (140); a signal probe DNA fragment (120) suitably adapted for hybridization with said target DNA (130); and a fluorescent bead (100) attached to said signal probe DNA (120). Disclosed features and specifications may be variously controlled, adapted or otherwise optionally modified to improve certain device fabrication parameters and/or performance metrics. (Emphasis added)



34. At paragraph [0015], Chapsky et al., disclose that a molecular motor can be F1-ATPase.

35. Chapsky et al., at paragraph [0019], teach that two different nuclei acids are hybridized to the target nucleic acid (applicant's first and second nuclei acids), and that they can comprise an affinity tag, e.g., biotin, which is used to bind a detection probe.

36. Chapsky et al., paragraph [0021], teach that the method allows for the detection of at least a single target nucleic acid of interest.

37. For the above reasons, the method of Chapsky et al., is deemed to anticipate the claimed invention. Accordingly, and in the absence of convincing evidence to the contrary, claims 1-7

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are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2003/0215844 A1 (Chapsky et al.)

38. Claims 1-7 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. US Patent Application Publication 2003/0215844 A1 (Chapsky et al.) discloses a method of detecting a target nucleic acid of interest using the same reagents *supra*. The inventorship of Chapsky et al., is different from that of the instant application. Accordingly, a question as to inventorship exists.

### ***Conclusion***

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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41. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/  
Primary Examiner, Art Unit 1634